

The Patent Office has made final its restriction requirement under 35 USC § 121. That being said, as a matter of procedure, the Patent Office is required to examine on the merits the entirety of the generic claims. MPEP § 809.02 mandates that the Patent Office performs a search for all claims readable on the elected species. If the elected species is found patentable, then subsequent species should be examined. If no species is found unpatentable, then the generic claim should be allowed. The MPEP does not authorize the Patent Office to derive its own concept of a genus from claim 1 and require that it be carved out of existing claims. Applicants look forward to all claims being considered in their entirety once patentability of the elected species is confirmed by the Patent Office.

The Patent Office has maintained its rejection under 35 U.S.C. § 112, second paragraph, because the phrase “pharmaceutically acceptable esters” is alleged to be indefinite.

Contrary to the position set forth in the Office Action, applicants’ claims fully satisfy the requirements of 35 U.S.C. § 112, second paragraph. The phrase “pharmaceutically acceptable esters” is definite and recited in numerous issued U.S. patents. The formation of pharmaceutically acceptable salts and esters of compounds is well known in the art and fully supported by applicants’ specification. While the phrase “pharmaceutically acceptable esters” may be broad, it is clearly definite as evidenced by the Patent Office’s issuance of numerous patents having claims containing such phrase.

In addition, applicants note that the specification at page 8, paragraph [0026], describes "pharmaceutically acceptable esters" as "esters of the compounds of formula (I), in which hydroxy groups have been converted to the corresponding esters....." Independent claims 1 and 24 properly embrace "pharmaceutically acceptable esters" of formula (I) and formula (Ia), respectively, because the substituents A² and R² of claim 1, and substituent A¹² of claim 24, may have hydroxy.

The Patent Office also maintained its objection of claims 1-7, 10-27, 42, 60, 62, 63, and 73-75 due to an allegedly improper Markush group. This objection stems from the Patent Office's determination that W and X are critical to the common core of the instant compounds. While applicants' appreciate the Patent Office's suggestion to amend the claims to read upon the elected group to overcome this objection, applicants are not making such an amendment at this time.

Applicants agree that W and X are critical to the common core of the claimed compounds. However, it is applicants' definition of W and X that should be controlling, not the Patent Office's definition. The Patent Office has no right to create a generic concept and require applicants to limit their invention to such concept. Accordingly, no objection under the doctrine of improper Markush group should be sustained.

The common theme of all of the above rejections and objections appears to be that the Patent Office would like to narrow applicants' claimed invention to limit its search burden. The Patent Office apparently seeks to achieve this by (i) an illegal intra-claim restriction (now made final), followed by (ii) denying applicants' examination of its entire claims on the merits (as required even if the restriction requirement were deemed

Serial No. 09/939,872
Filed: August 27, 2001

proper), coupled with (iii) an objection based on improper Markush group (based on the Patent Office's concept of the invention), and (iv) a rejection for indefiniteness (based on a phrase that has appeared in numerous U.S. patents). Although such approach may be pragmatic, it does not reflect current U.S. law.

In view of the above, applicants request reconsideration, withdrawal of all rejections under 35 U.S.C. §112, second paragraph, and all objections based on improper Markush group.

Claims 1-6, 8-27, 42-44, 59-63, 67-71, and 73-75 were rejected as allegedly being anticipated by Aebi (U.S. Patent No. 6,034,275).

This is incorrect. The compounds disclosed in Aebi are not claimed in the subject application despite the assertion in the Office Action that "Aebi anticipate the instant claims when W or X represents SO_2 , n is 0 and V represents 0 in the compounds of formulae (I) or (Ia)."

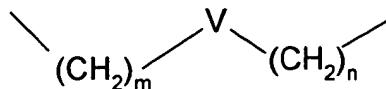
The central portion of the Aebi compound of formula I is:

$-\text{L}-(\text{M})_p-\text{T}-$

When $p=1$, L is " $\text{C}_4\text{-C}_{11}$ alkylene which has at least 4 C atoms between the two free valencies," M can be M^1 connected to L via O {q in M^1 is 0}, and T can be SO_2 {allowed if q is 0}. This represents the compound that is structurally closest to

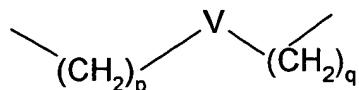
applicants' claimed compounds. As you can see, there are **at least 4 C atoms** between the left portion of the molecule at the O that connects L to M.

In contrast, applicants' claim 1 (formula I) contains in its central portion:



This claim requires "m is 1 to 3 when V is O, W is CO or SO₂, and n is 0." Therefore, there are **only 1 to 3 C atoms** between the left portion of the molecule and the O at position V.

Likewise, claim 24 (formula Ia) contains in its central portion:



This claim requires "p is 1 to 3 when V is O, X is CO or SO₂, and q is 0." Therefore, there are **only 1 to 3 C atoms** between the left portion of the molecule and the O at position V.

Accordingly, there is no overlap between the molecules disclosed by Aebi and those claimed in the subject application, and thus no grounds for rejection under 35 U.S.C. § 102.

Serial No. 09/939,872
Filed: August 27, 2001

In view of the above, applicants request reconsideration, withdrawal of all rejections under 35 U.S.C. § 112 and 102, and the issuance of a Notice of Allowance.

If a telephone conference would be of assistance in furthering prosecution of the subject application, applicants request that the undersigned attorney be contacted at the number below.

No fee, other than the fee for a two-month extension of time, is required in connection with the filing of this Response. If any additional fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,



Attorney of Applicants
John P. Parise
(Reg. No. 34403)
340 Kingsland Street
Nutley, New Jersey 07110
Telephone: (973) 235-6326
Telefax: (973) 235-2363

127291